

REMARKS

Claim 46 has been cancelled. The amendment to claim 35 is supported by claim 46. Claim 36 has been amended to be consistent with the amendment to claim 35. Claims 43 and 47 have been placed into independent form. Claim 77 is supported by claim 76. No new matter has been added. Claims 35-37, 40, 41, 43, 47, 76 and 77 are present and active in the application.

Applicants thank Examiner Tongue for the courteous and helpful discussion held with applicants' representative on March 9, 2010. During this discuss applicants' representative sought clarification of the § 112, 1st paragraph enablement rejection solely over claim 46, particularly since the claim it depends from (claim 35) and the claim which depends from it (claim 47) were not so rejected.

Applicants also thank Examiner Tongue for withdrawal of previous rejections under §§102 and 103 over Slopek et al., as well as the previous rejections of the claims (except claim 46) under § 112, 1st paragraph.

Rejection under 35 U.S.C. §§ 102 and 103

The rejections of claims 35-37, 40 and 41 as anticipated under 35 U.S.C. § 102, and claim 76 as obvious under 35 U.S.C. § 103, over Sharp et al., have been obviated by appropriate amendment. Claim 46 has been incorporated into claim 35, from which claims 36, 37, 40, 41 and 76 depend. Withdrawal of these grounds of rejection is respectfully requested.

Rejection under 35 U.S.C. § 112

The rejection of claim 46 under 35 U.S.C. § 112, 1st paragraph has been obviated by the filing of deposit receipts for NCIMB 41174, NCIMB 41175, NCIMB 41176, NCIMB 41177, NCIMB 41178 and NCIMB 41179. Withdrawal of this ground of rejection is respectfully requested.

The rejection of claim 46 (now in independent form as claim 35) under 35 U.S.C. § 112, 1st paragraph, as lacking enablement, is respectfully traversed.

Initially, applicants note that the prior Office Action indicated that this rejection was based on the language in claim 46 referring to “a variant” of bacteriophages in the panel, which was removed in the prior response. According, applicants request clarification of the nature of this rejection, if it is maintained. Applicants nevertheless provide arguments traversing this rejection of claim 46 (now in independent form as claim 35).

Applicants note that specification provides sufficient descriptions of how to make and use the claimed invention to provide enablement of the claimed invention. Claim 46 (now in independent form as claim 35) includes two portions: (a) administration of one or more preparations comprising specific bacteriophages, and (b) administration of one or more antibiotics. The administration of antibiotics is well known to those of ordinary skill in the art, and thus no specific description is needed to provide enablement for administration of one or more antibiotics. In addition, the timing of antibiotic administration is described in the first paragraph of page 10.

Furthermore, the application contains extensive descriptions of how to make and use preparations containing bacteriophages of the claimed invention. Identification and selection of the bacteriophages is described on pages 10-11. Growth of the bacteriophages is described on page 12. Preparation of pharmaceutical compositions containing the bacteriophages, for a variety of administration routes, is described on page 13. Use of the preparations for chronic or resistant infections is described on page 17. Types of infections that can be treated by the claimed method are described on pages 18 and 22. Page 18 also describes preparations containing bacteriophages in combination with other therapeutic agents. Dosages and routes of administration are described on pages 19-20. Examples of using the preparations containing bacteriophages for treatment of internal infections (page 34), skin wound infections (page 34), infections of skin grafts and burns (pages 35 and 37), and ear infections (pages 35, and 38-41) are also present in the application. Applicants submit that this extensive description of how to make and use the claimed invention is sufficient for enablement.

The examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure (MPEP § 2164.04, citing *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Furthermore, a specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support (MPEP § 2164.04, citing *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971)). "It is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure." MPEP § 2164.04, citing *In re Marzocchi*, 439 F.2d at 224, 169 USPQ at 370. Accordingly, applicants submit that the present specification is sufficient to enable the claimed invention. Withdrawal of this ground of rejection is respectfully requested.

CONCLUSION

All of the grounds raised in the present Office Action for rejecting the application are believed to be overcome or rendered moot based on the remarks above. Thus, it is respectfully submitted that all of the presently presented claims are in form for allowance, and such action is requested. Should the Examiner feel a discussion would expedite the prosecution of this application, the Examiner is kindly invited to contact the undersigned at (312) 876-1400.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Paul E. Rauch', is written over a horizontal line.

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